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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,945	02/16/2005	Farhad Parhami	58086-241892	3129

26694 7590 02/28/2008

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
02/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,945	PARHAMI, FARHAD	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Applicant's response to restriction requirements of October 02, 2007 is fully responsive and has been entered. Applicant's election of Group I drawn to claims 1-36, without traverse, is acknowledged. Please, note that the examiner of this application has changed and is no longer Sreeni Padmanabhan but Maria Leavitt.

Upon reconsideration of the claims under different premises, a further restriction is required from the following Groups:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claim(s) 1-28, are drawn to a method of inducing or inhibiting differentiation of mammalian mesenchymal stem cells with at least one oxysterol.

II. Group II, claim(s) 29-36, are drawn to a method of treating a patient to induce bone formation comprising harvesting mammalian mesenchymal cells, treating said cells with at least one oxysterol to induce osteoblastic differentiation and administering the differentiated cells to the patient.

III. Group III, claim(s) 37-40, are drawn to an implant for use in the human body, wherein at least one surface includes at least one oxysterol.

IV. Group IV, claim(s) 41, is drawn to a medicament comprising at least one oxysterol.

The inventions listed as Groups I - IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

37 CFR 1.475 (c) states:

> "If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

> "If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-IV appears to be that they all relate to agents and methods for inducing osteoblastic cellular differentiation and methods to treat patients to enhance bone formation. However, prior art has taught the use of 25-hydroxycholesterol as a treatment in order to study mitogenic effects and is known as a medicament (Larsson et al., Cancer Research, 1986). Therefore, the technical feature linking the invention of groups I-IV

does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

Inventions of **Group I drawn to** a method of inducing or inhibiting differentiation of mammalian mesenchymal stem cells with at least one oxysterol are structurally and functionally different from inventions of **Group II** drawn an *ex vivo* method of treating a patient to induce bone formation, said methods having different steps, physical properties and biological functions. For example, Inventions of Group II required isolation of mammalian mesenchymal cells, treatment of said cells with at least one oxysterol to induce osteoblastic differentiation and administration of the differentiated cells to the patient, which steps are not claimed or required by the inventions of Group I. Moreover, Inventions of Group III drawn to an implant include unique technical features that are not shared by the inventions of Groups IV drawn to a medicament. Because these inventions are distinct for the reasons given above, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Species restriction

Should Groups **I, II or VI** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) A genus of molecules as recited in claims 2, 7, 14, 16, 20, 25, 30 and 41 selected from one of the following oxysterols:

20S-hydroxycholesterol, 22S- hydroxycholesterol, 22R-hydroxycholesterol, 25-hydroxycholesterol, or pregnanolone, or an active portion of any one of 20S-hydroxycholesterol, 22S- hydroxycholesterol, 22R-hydroxycholesterol, 25-hydroxycholesterol, or pregnanolone.

The species are independent or distinct because there are oxysterols having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 6, 13, 15, 24, 29 and 37 are generic.

Should Groups **I or II** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

2) A genus of molecules as recited in claims 3, 8, 17, 21, 26 and 31 selected from one of the following combination of oxysterols:

20S- hydroxycholesterol and 22R-hydroxycholesterol, or 20S-hydroxycholesterol and 22S-hyd roxycholesterol.

The species are independent or distinct because there are combination of oxysterols having different chemical structures, physical properties, and biological functions. Thus, the

combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 6, 13, 15, 24, 29 and 37 are generic.

3) A genus of molecules as recited in claims 4, 5, 9, 10, 18, 22, 23, 27, 28, 33 and 34 selected from one of the following secondary agents:

parathyroid hormone, sodium fluoride, insulin-like growth factor I, insulin-like growth factor II or transforming growth factor beta, cytochrome P450 inhibitors, phospholipase activators, arachadonic acid, COX enzyme activators, osteogenic prostanoids or ERK activators, bisphosphonates, selective estrogen receptor modulators, calcitonin, or vitamin D and calcium.

The species are independent or distinct because there are secondary agents having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 6, 13, 15, 24, 29 and 37 are generic.

Should Groups **I** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

4) A genus of biological markers as recited in claim 11 selected from one of the following:

alkaline phosphatase activity, calcium incorporation, mineralization or expression of osteocalcin mRNA.

The species are independent or distinct because there are biological markers having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 6, 13, 15, 24, 29 and 37 are generic.

5) A genus of mammalian cells as recited in claim 12 selected from one of the following:

mesenchymal stem cells, osteoprogenitor cells or calvarial organ cultures.

The species are independent or distinct because there are mammalian cells having different chemical structures, physical properties, and biological functions as the result of having different genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 6, 13, 15, 24, 29 and 37 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD

Examiner, Art Unit 1633